OMB Peer Review Guidelines: Implications for the NTP May 2005

In December 2004, the Office of Management and Budget (OMB) issued the Final Information Quality Bulletin for Peer Review (OMB Bulletin). The OMB Bulletin establishes minimum standards for peer review "of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the federal government" and provides defined standards for disseminations considered "influential scientific information" or "highly influential scientific information." The NTP has reviewed the OMB Bulletin and, in consultation with Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), identified several documents that would likely be subject to pre-dissemination peer review of the draft documents. These documents include: (1) draft NTP Technical Reports, (2) draft Background Documents for nominations to the Report on Carcinogens, (3) draft listing profiles for new entries to the Report on Carcinogens, (4) draft NTP Briefs in NTP-Center for the Evaluation of Risks to Human Reproduction (CERHR) Monographs and (5) draft Background Review Documents from the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The NTP would clarify that its opinion communicated in any of these draft documents is not subject to the OMB Bulletin, rather, the OMB Bulletin addresses peer review of the scientific information upon which that opinion is based.

The NTP has carefully examined these documents and recognizes that while all contain scientific information, they would not necessarily all meet the classification of "influential scientific information" or "highly influential scientific information" for a specific environmental agent as defined by the OMB Bulletin. It should be noted that the NTP, on a case-by-case basis, would examine the draft document for a specific environmental agent and determine whether it meets either classification. However, considering all ramifications of the standards outlined in the OMB Bulletin, the NTP has submitted to HHS and NIH for their review, proposed processes for peer review of each of the documents identified above classifying them as either "influential scientific information" or "highly influential scientific information" based upon an initial assessment of each document type.

The NTP proposes to present an overview of the OMB Bulletin to the NTP Board and discuss its implications for the NTP and how the NTP proposes to meet the standards required for pre-dissemination peer review. It is our intent to send additional information to the NTP Board prior to the meeting once review by HHS and NIH is completed.

¹ 70FR2666, included in your background materials for peer review

² "means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions"

³ "influential scientific information the the agency or Administrator [of the Office of Information and Regulatory Affairs in OMB] determines to be a scientific assessment that: (1) could have a potential impact of more than \$500 million in any year, or (ii) is novel, precedent-setting, or has significant interagency interest."